

## **REMARKS**

Claims 1-32 are pending and stand rejected. Claim 20 has been amended. Applicant respectfully requests reconsideration of the rejection in view of the amendment and the following remarks.

### **The 35 U.S.C. §112 Claim Rejection**

Claim 20 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Action stated that the limitation "the porous polymer prosthesis" is without antecedent basis. Applicant respectfully submits that the amendment to claim 20 renders this rejection moot.

Before addressing the details of the prior art rejections, applicant believes that a quick overview of the invention is useful. The claimed invention describes a technique for making shaped (such as molded) porous polymeric articles. In essence, what one does is, for any given (solid) polymer, one identifies two liquids, both referred to as "solvents". The first solvent is truly a solvent in the traditional sense of the term in that it is capable of dissolving the polymer. The second solvent cannot dissolve the polymer to any appreciable extent; it merely swells solid polymer. One proceeds from here by dissolving the polymer in the first solvent, and then adding quantities of the second solvent to the solution. This causes the solution to increase in viscosity, eventually gelling the solution. At the desired viscosity, the solution is then molded or otherwise shaped, and finally the two solvents are removed, which leaves behind the solid polymer, but in shaped and porous form.

### **The 35 U.S.C. §102 Claim Rejections**

Claims 1, 2, 4, 12, 15-17, 25, 26, 29 and 31 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,492,154 to Einstman (hereinafter referred to as "Einstman"). Applicant respectfully traverses this rejection.

The Action is correct that Einstman discloses adding a second solvent to the polyurethane solution. However, Einstman's second solvent is actually a non-solvent, as the applicant uses the term. Among the non-solvents that Einstman discloses as adding to his solution are chloroform and water, with water being particularly preferred. Einstman's use of the term "non-solvent" appears to have the same meaning as applicant's use of that term, in particular, a substance that causes coagulation or precipitation of solid polymer from solution (see, for example, page 4, lines 32-34). Apparently, the system can tolerate small quantities of added non-solvent; But when added in excess, this non-solvent would coagulate the solution (see, for example, col. 6, lines 68-73). However, Einstman prefers to coagulate his solution to precipitate out solid polymer (after applying the solution to his substrate) by reducing the

temperature. Prior to applying the solution to the porous substrate, Einstman does not want gelation (see, for example, col. 6, lines 2-4). Einstman takes the solution close to gelation or coagulation by adding only about 70 to 98% of that amount that would cause gelling, determined through experimentation, applying the combined solution to a substrate, and then coagulating by reducing the temperature.

Thus, the Einstman process is different from the claimed process because Einstman does not want gelation prior to applying the solution to the substrate. Furthermore, Einstman's non-solvent is not the claimed gelling or swelling solvent that applicant uses as his second solvent. Accordingly, applicant respectfully submits that this rejection should be withdrawn.

Claims 1-3, 11-13, 15, 17, 25-27, 29, 30 and 32 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,553,008 to Reischl (hereinafter referred to as "Reischl"). Applicant respectfully traverses this rejection.

Reischl is similar to Einstman, but Reischl leaves open the possibility (although not his preferred embodiment) of sufficiently coagulating his solution to form a gel, and then working with the gel to make a shaped article, here a porous sheet. But like Einstman, the second solvent of Reischl is not a swelling or gelling solvent as claimed in the present application, but instead merely a non-solvent. Again, the non-solvent is really an extracting solvent, which extracts the dissolving solvent, thereby causing solid polymer to precipitate ("crash") out of solution.

There is further evidence that the non-solvent of Reischl is not the same as applicant's gelling solvent, but rather is consistent with applicant's use of the term "non-solvent": he furthermore describes the gel that is formed as being "opaque" (col. 5, line 26). This opaqueness suggests that a solid is precipitating. Accordingly, Reischl suggests filtering the combined solution (polymer plus solvent plus non-solvent) through a copper gauze (col. 5, lines 51-56). In contrast, the examples of the claimed invention do not describe such a filtering process because there was nothing to filter; the solution remained homogeneous. In view of this significant difference, applicant respectfully submits that the non-solvent of Reischl is what he says it is, and therefore it is patentably distinct from applicant's gelling solvent. Accordingly, applicant respectfully requests that this rejection be withdrawn.

Claims 1, 8, 10, 15, 16, 23, 24, 26, 27, 29, 31 and 32 were rejected under 35 U.S. C. §102(b) as being anticipated by U.S. Patent No. 5,077,049 to Dunn (hereinafter referred to as "Dunn"). Applicant respectfully traverses this rejection.

Dunn discloses a process for making a porous polymeric implant. A polymer is dissolved in one or more solvents. Other substances such as biologically active agents may be added to the solution, and then the solution is injected or implanted into a living being, where the body fluid (e.g., saline) acts as a coagulating solvent to extract the dissolving solvent(s) and solidify the polymer in porous form. Dunn discloses a large list of candidate polymers and solvents (see, for example, col. 5, lines 10-51), including polyurethane, tetrahydrofuran (THF) and

dimethyl sulfoxide (DMSO). However, Dunn neither discloses nor suggests this particular combination, nor the order of solvent addition. In fact, there is no apparent appreciation in Dunn that any of his "solvents" might perform any functions (e.g., gelation) other than to dissolve the polymer, or to precipitate solid polymer. Dunn raises the possibility of using multiple solvents, but it appears to be for the purpose of engineering the solution to be right on the edge of "criticality" so that solid porous polymer precipitates out as soon as the solution contacts his coagulating solvent (see for example, col. 6, lines 3-10). Applicant respectfully submits that Dunn neither discloses nor suggests any kind of the claimed gelation phenomenon; that is, gelation without polymer precipitation (see, for example, page 5, lines 46-48). Accordingly, applicant respectfully requests that this rejection be withdrawn.

### The 35 U.S.C. §103 Claim Rejections

Claims 6, 7, 9, 11, and 18-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Einstman in view of U.S. patent No. 5,447,724 to Helmus et al. (hereinafter referred to as "Helmus") and U.S. patent No. 4769,286 to Le Noane (hereinafter referred to as "Le Noane"). Applicant respectfully traverses this rejection.

Applicant respectfully submits that the claimed process is patentable over the cited references. As recited above, Einstman neither discloses nor suggests the claimed gelation step (Einstman avoids gelation), and furthermore, Einstman's second solvent is a non-solvent that, in sufficient quantity, causes coagulation; it is different from the claimed gelling or swelling solvent that applicant uses as the second solvent. Helmus discloses medical devices where a surface comprises a porous polymeric composition holding a biologically active compound. Le Noane discloses reinforcing materials such as fibers, rings, and other devices. However, neither Helmus nor Le Noane disclose or suggest the claimed features (e.g., gelling solvent and gelling phenomenon) that are missing from Einstman; thus, Helmus and Le Noane fail to remedy the deficiencies of Einstman. Accordingly, applicant respectfully requests that this rejection be withdrawn.

Claims 14 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn in combination with Reischl. Applicant respectfully traverses this rejection.

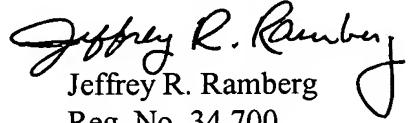
Reischl discloses a gelation phenomenon, but it utilizes a non-solvent. This gelation seems to be the by-product or consequence of the coagulation of the polymer by the non-solvent, and it is accompanied by opaqueness and polymer precipitates, possibly requiring the filtration of the precipitate. Reischl fails to disclose or suggest the gelling solvent of the claimed invention. Although Dunn discloses DMSO, he uses it as a dissolving solvent, and seems completely unaware that, under the right conditions, it can act as a gelling solvent. (Of course, under different conditions, e.g., different polymers, DMSO could be a dissolving solvent, or neither gelling nor dissolving solvent.) With all due respect to the position of the Action, applicant can find no passage in Dunn that indicates or even suggests anything about

gelation. Thus, applicant is of the opinion that Dunn fails to remedy the deficiency of Reischl. Accordingly, applicant respectfully requests that this rejection be withdrawn.

In view of the amendments and the above remarks, applicant respectfully submits that the present application is in condition for allowance. Accordingly, applicant respectfully requests issuance of a Notice of Allowance directed to claims 1-32.

Should the Examiner deem that any further action on the part of applicant would be desirable, the Examiner is invited to telephone applicant's undersigned representative.

Respectfully submitted,

  
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